Clinical Pathways in General Surgery

Development, Implementation, and Evaluation

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Summary

Objectives: To emphasize the importance of the view of business process management for development and implementation of clinical pathways, and to evaluate their effectiveness in reducing cost and effort as well as enhancing patient satisfaction.

Methods: We describe the development and implementation of pathways with methods of process management and the design and realization of an evaluation study in the setting of a surgical department. For this study 67 patients treated without clinical pathways were compared with 62 patients treated using pathways.

Results: The approach explicitly enhances the development and implementation of clinical pathways. The introduction of pathways reduces length of hospital stay, number of laboratory tests, number of consultations, and number of imaging procedures. Patient satisfaction is improved.

Conclusions: Depending on design and setting, the introduction of clinical pathways may be a very promising method to improve the inpatient service at a hospital and so to react to the challenges of increasing competition in medical care.

Keywords
Patient care planning, critical pathways, clinical pathways, process management, evaluation

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Introduction

The increasing competition in medical care together with the need to reduce cost yielded initiatives for the reengineering of health care processes. An approach often applied in hospitals is the introduction of clinical pathways.

Clinical pathways – also known as critical pathways, care pathways, or integrated clinical pathways – are patient care algorithms based on best evidence. They are intended to minimize variance in treatment and thus reduce cost, increase efficiency, and ultimately improve patient care outcomes [1]. They are designed by multidisciplinary cooperation and implemented by organizational and technical measures, i.e. mainly specific IT-support. This definition emphasizes the most important properties and goals of a pathway: it is an evidence-based method for patient care management, by which standardization of treatment, cost reduction, and improvements in organization and outcome shall be achieved. However, there is some ambiguity about their usefulness and impact [2, 3].

In this paper we will outline important requirements for the successful development and implementation of pathways. Furthermore we will present the results of an evaluation study performed to assess the effects of pathways on workflow and patient satisfaction.

Clinical Pathways and Process Management

A clinical pathway may be regarded as a special form of a core (business) process at hospitals [4], whereas core processes imply the delivery of inpatient care: a patient’s request starts a cascade of activities (or steps), resulting in the supply of patient care. Each process needs resources and creates indicators that enable monitoring and controlling.

The business process management (BPM) is responsible for purposeful planning, direction, and controlling of business processes. BPM has three different levels: the strategic, tactical, and operational level. The strategic level comprises the tasks of defining objectives, planning processes and their interactions, and providing resources. Design and implementation of processes are the tasks on a tactical level. They are performed in the form of projects, which need accurate project management. Operational BPM is responsible for maintaining the processes. It has to care for their operation in accordance with the strategic objectives.

The main objectives of BPM are customer (patient) satisfaction, quality enhancement, reduction of time and cost, and improvement of scheduling. Their achievement is measured by indicators, which may be used as outcome variables to evaluate the effectiveness of pathways. Examples are availability of a contact person (patient satisfaction) or length of hospital stay (time and cost).

A clinical pathway has four major components [4]. The theory covers medical practice, guidelines, hospital protocols, and best evidence references. The process is described (among other) by starting- and endpoint, inclusion and exclusion criteria, conditions, and sequence of tasks (workflow). The documentation comprises pathway-related documents, patient-related documents (e.g. discharge summary), and information material for the patient. For controlling and
Fig. 1 Part of the graphical representation of the pathway “Secondary malignant neoplasm of liver”
quality management specific characteristics and procedures (e.g., cost accounting) are necessary.

The development of a pathway involves building these components. The theory must be compiled from several sources and logically edited. Today there are integrated tools to build the remaining components simultaneously. Paper-based tools (task-flow, control flow, resources, and responsible units and persons) may be used as templates. A pathway can be represented as a flowchart that describes the actions, data flow, control flow, resources, and responsible units and persons (Fig. 1).

The development of pathways is an iterative process with a feedback mechanism. Test facilities like syntax checks, dummy runs, and function tests should also be provided by a software tool. Additionally, organizational measures have to be planned and simulated. Daily monitoring and periodic controlling mechanisms allow to detect pathway violations (i.e., delay or break) and to estimate pathway’s variance. A concept for continuous education of all staff members who will be involved in any component of the pathway has to be developed and implemented.

### Local Implementation

Since 2004, at the department of General Surgery, Abdominal and Vascular Surgery, and Pediatric Surgery of the Saarland University Hospital, clinical pathways have been introduced using the approach described above. The steering committee (head of department, senior staff surgeon, chief nurse, computing officer of department) acts at the strategic level of BPM. It has to define objectives, time limits, milestones, priorities, granularity (i.e., how exactly the actions, times, and conditions of a pathway are detailed), consensus procedures, and provide resources.

The members of the pathway team (tactical level) are a senior staff surgeon, four surgeons, four nurses, and the computing officer. This team is responsible for design, development and introduction of pathways and the appropriate project management. At the operational level the computing officer and other members of staff provide the daily process monitoring and mechanisms periodically carried out to control assignments and violations of pathways.

The hospital information system (HIS) software consists of several modules of R/3 (SAP, Walldorf, Germany) including the patient data management system IS-H. The product i.s.h.med (GSD, Berlin, Germany) delivers the medical applications including order entry, documentation, and electronic patient record via a common user interface (clinical workstation, CW). It is integrated completely with the R/3 modules by access to one common database (data integration).

i.s.h.med pathways (GSD, Berlin, Germany) is an additional module for creating and managing clinical pathways, i.e., it upgrades i.s.h.med with facilities for process analysis, modeling, graphical presentation, test, implementation, pathway assignment, instantiation, and scheduling via the user interface of CW. This allows the development and test in form of rapid prototyping as well as complete workflow integration, since links to medical functions (e.g., order, access to electronic patient record, documentation) are available directly: the physician can choose and assign the relevant pathway, execute stepwise, and control the workflow with a minimum of navigations.

Figure 1 shows an example of the graphical map of a pathway created with the graphical editor. The minimal step is one day. Denotation and duration of pathways comply with the requirements of the German system for Diagnoses Related Groups (G-DRG).

The basis of pathway documentation is called clinical guideline. It is developed by the pathway team using general guidelines, department standards, and evidence-based information from the medical literature. The pathway-related documentation is called clinical information.

### Evaluation Study

To assess the effectiveness of clinical pathways in this setting we performed a prospective observational study with before-after design. Between 01.06.2005 and 30.09.2005 67 patients with six different diagnoses (Table 1) were treated without clinical pathways (group 1, “before”). Between 01.10.2005 and 28.02.2006 62 patients with the same diagnoses were treated using clinical pathways (group 2, “after”). Only elective patients providing informed consent were included. The patients did not know to which group they belonged.

To obtain a sufficient number of cases the selection of diagnoses resp. pathways based on the number of patients in 2004. Furthermore different levels of complexity corresponding to the number of pathway steps (Table 1) were considered, and the pathways had to be implemented on time before their start on 01.10.2005.

The primary outcome measure was the length of hospital stay (LOS). The numbers

### Table 1 Number of patients for each diagnosis (ICD10-code) resp. pathway

<table>
<thead>
<tr>
<th>Diagnosis/pathway</th>
<th>Group 1 (n = 67)</th>
<th>Group 2 (n = 62)</th>
<th>Number of pathway steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventral hernia without obstruction or gangrene (K43.9)</td>
<td>13 (19.4%)</td>
<td>19 (30.6%)</td>
<td>29</td>
</tr>
<tr>
<td>Atlantoaxial dislocation of arteries of lower extremities (I70.2)</td>
<td>5 (7.5%)</td>
<td>6 (9.7%)</td>
<td>32</td>
</tr>
<tr>
<td>Malignant neoplasm of colon (C18)</td>
<td>16 (24.9%)</td>
<td>14 (22.6%)</td>
<td>38</td>
</tr>
<tr>
<td>Malignant neoplasm of pancreas (C25)</td>
<td>9 (13.4%)</td>
<td>8 (12.9%)</td>
<td>40</td>
</tr>
<tr>
<td>Chronic pancreatitis (K86.0, K86.1)</td>
<td>14 (22.6%)</td>
<td>9 (14.3%)</td>
<td>22</td>
</tr>
<tr>
<td>Aortic aneurysm and dissection (I71)</td>
<td>9 (13.4%)</td>
<td>7 (11.3%)</td>
<td>54</td>
</tr>
<tr>
<td>Secondary malignant neoplasm of liver (C78.7)</td>
<td>15 (22.4%)</td>
<td>8 (12.9%)</td>
<td>64</td>
</tr>
</tbody>
</table>

Legend: Pathway with

- low complexity
- medium complexity
- high complexity

Number of patients for each diagnosis (ICD10-code) resp. pathway.
of consultations, laboratory tests, and imaging procedures were used as surrogate variables for cost and effort. The patient satisfaction was assessed through a questionnaire with 25 items based on the validated survey method ZUF-8 [7] with adaptations for clinical pathways.

Data were collected from the electronic patient record, the paper-based patient record, and through the patient questionnaire, that was filled out by the patients immediately before their discharge. All data were stored anonymously in a study database.

**Results**

Since the start in 2004 the methods could be refined stepwise. This fact and the increasing experiences with existent pathways reduced the time for development and implementation from several days at start to 8 to 10 hours (after the clinical guideline is completed). Up to now 20 clinical pathways have been implemented. More than 1000 patients have been treated so far using pathways.

In group 1 67 patients (48 (71.8%) male) and in group 2 62 patients (38 (61.3%) male) were observed. The mean age was 64.7 (SD 9.7) in group 1 and 62.0 (SD 12.7) in group 2. The dropout rate in group 2 was 27 from 62 (43.5%). Reasons were occurring complications, delay of operation or wound healing, retarded postoperative oral feeding, and organizational problems in the starting phase of a pathway. Table 1 shows the number of patients for the six selected diagnoses resp. pathways.

LOS is listed in Table 2 overall and for subgroups. The median is added because LOS is not normally distributed. Except pathways with high complexity, LOS in group 2 is smaller than in group 1. The difference in overall LOS between group 1 and group 2 (12.9 d vs. 11.1 d) is statistically significant (Mann-Whitney U-test, \( p \leq 0.05 \)).

The mean number of laboratory tests in group 1 is much higher than in group 2 (overall 24.5 vs. 9.3, clinical chemistry parameters 6.9 vs. 2.8, coagulation parameters 5.2 vs. 2.1, and blood count 8.0 vs. 3.2). Figure 2 shows bar charts to compare the groups with regard to the number of consul-

![Fig. 2](https://example.com/fig2.png)

**Table 2**

<table>
<thead>
<tr>
<th>Pathway complexity</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>67</td>
<td>62</td>
</tr>
<tr>
<td>Before OP</td>
<td>2.6 ± 3.8, 1.0</td>
<td>1.4 ± 0.9, 1.0</td>
</tr>
<tr>
<td>After OP</td>
<td>10.3 ± 6.6, 9.0</td>
<td>9.7 ± 8.5, 7.0</td>
</tr>
<tr>
<td>Low complexity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathway completed</td>
<td>10.4 ± 6.3, 8.5</td>
<td>6.7 ± 2.3, 7.0</td>
</tr>
<tr>
<td>Pathway stopped</td>
<td>14.1 ± 8.4, 12.0</td>
<td>11.6 ± 4.3, 10.0</td>
</tr>
<tr>
<td>Medium complexity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathway completed</td>
<td>14.5 ± 8.4, 12.0</td>
<td>11.6 ± 4.3, 10.0</td>
</tr>
<tr>
<td>Pathway stopped</td>
<td>13.8 ± 6.8, 13.5</td>
<td></td>
</tr>
<tr>
<td>High complexity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathway completed</td>
<td>13.1 ± 6.8, 11.0</td>
<td>16.4 ± 13.8, 11.5</td>
</tr>
<tr>
<td>Pathway stopped</td>
<td>8.0 ± 6.6, 10.5</td>
<td>20.3 ± 18.2, 11.5</td>
</tr>
</tbody>
</table>

![Fig. 2](https://example.com/fig2.png)

**Fig. 2** Number of consultations and number of imaging procedures (x-ray, CT, NMR, ultrasonography) per patient
tations resp. number of imaging procedures. Both figures in group 2 are significantly smaller than in group 1. The mean time up to forwarding the complete discharge summary was 15.5 d (SD 19.3, median 10.0) in group 1 and 10.5 d (SD 9.2, median 7.0) in group 2.

Selected items from the questionnaire evaluating patient satisfaction are presented in Table 3. Most items are better assessed in group 2 than in group 1.

### Discussion

Development, implementation, and effectiveness of clinical pathways are discussed controversially [2, 5, 8, 9]. According to the list of Brender et al. [10] we could identify the following success factors:

- **Managerial factors:** effective support by the head of department and hospital’s managing board, continuous change management, good and flexible project management

- **Organizational factors:** interdisciplinary teams according to the three levels of BPM, continuous education of staff, “bridgers” who interface directly with users [11]

- **Functional and technical factors:** standardized form of clinical guidelines, powerful tools for process analysis, pathway representation, and rapid prototyping, automatic workflow control after instantiation, comprehensive HIS integration with interfaces to all medical functions

The introduction of clinical pathways must be embedded in a strategic management framework, including process management, project management, and change management [12]. We recommend especially the consideration of the organizational factors for similar projects.

The definition and use of standardized guidelines as the basis of pathway documentation and a careful analysis of clinical processes are very important. These tasks require interdisciplinary teamwork and comprehensive software support. The workflow integration – a critical factor in the acceptance and use of computer systems [9] – will be achieved by “anchoring” pathways in the clinical workstation software. This is a significant advantage of the software described, because it provides a uniform user interface with fast access to all functions of CW and electronic patient records.

To assess the effectiveness of clinical pathways a before-after comparison is the best available design. However doubts can remain how much the groups are comparable, i.e. it is unknown if the intervention is the single explanatory variable [8]. The conditions have to be analyzed exactly and secular trends must be discussed [13].

Decrease of LOS is reported quite frequently [8, 14]. This effect could be verified in this study, as well overall as before and after operation. The LOS increased only for pathways with high complexity, since some dropouts had an extremely extended LOS. The decrease of laboratory tests, consultations, and imaging procedures as well as the faster availability of discharge summaries show that the improvement of workflow and cooperation may lead to a reduction of effort and cost. This effect does not occur at the expense of patient care and satisfaction, as other investigations show similarly [14].

### Conclusions

The results of the evaluation study show that careful business process reengineering via clinical pathways reduces effort and cost and improves patient satisfaction. Decision support, more transparency, and use as a learning aid for beginners are additional advantages of pathways. Hence this approach may help hospitals in reacting on the challenges of increasing competition in medical care.

### Acknowledgments

The authors declare that there are no competing interests.

### References

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